Exhibit A

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612

Telephone: 949-608-2900
Fax: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

July 13, 2015

W/L # 27-15

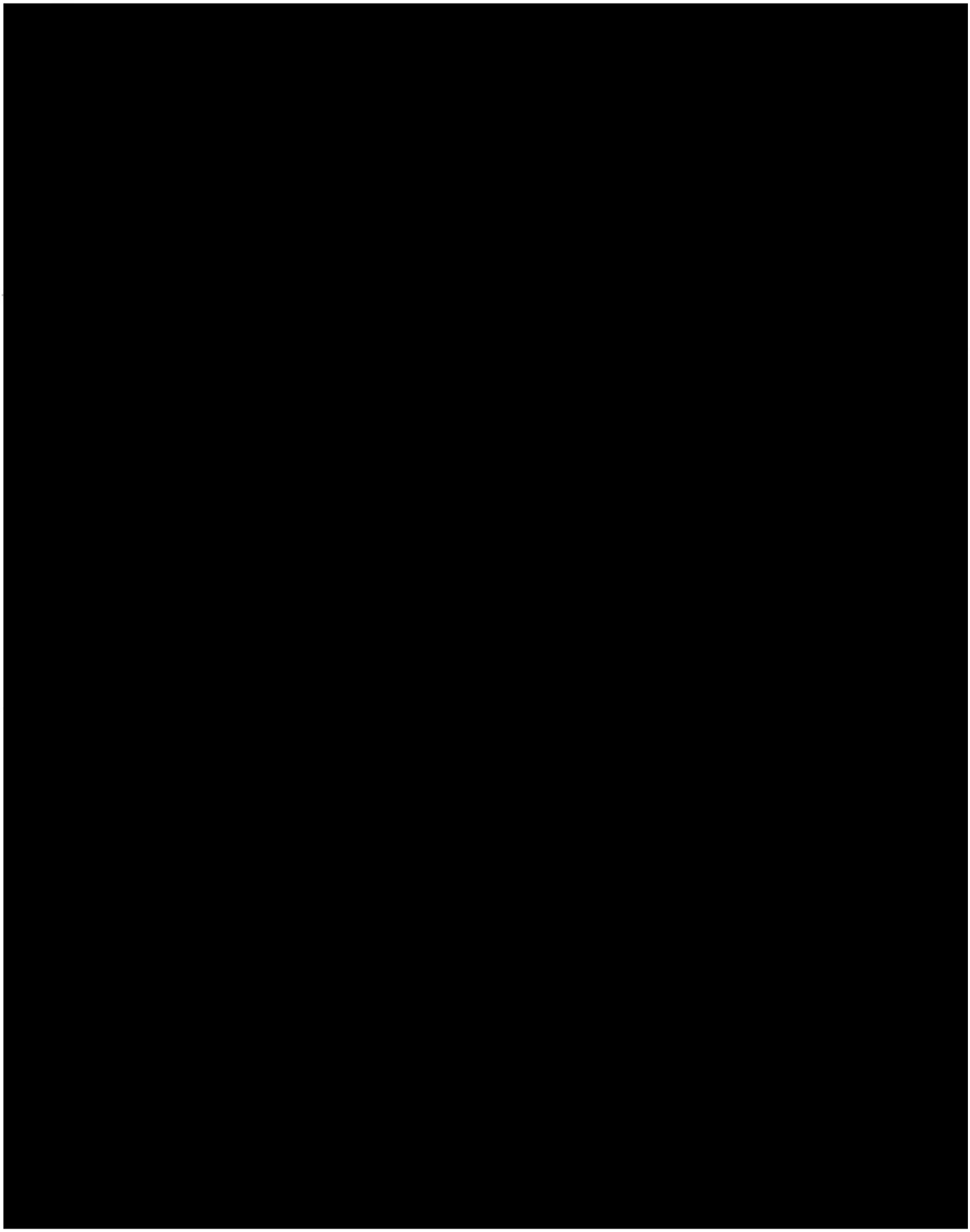
Timothy M. Ring
Chairman and Chief Executive Officer
C.R. Bard Inc.
730 Central Ave.
Murray Hill, NJ 07974

Dear Mr. Ring:

During inspection of your C.R. Bard Inc. facility located at 289 Bay Rd, Queensbury, NY, on October 6, 2014, through November 25, 2014, and during inspection of your Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ, on November 18, 2014, through January 05, 2015, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a specification developer and manufacturer for the Inferior Vena Cava (IVC) filter delivery systems and components, including, but not limited to, the Denali Filter, the Simon Nitinol Filter and Recovery Cone Removal Kit. This warning letter addresses violations found at the Bard Peripheral Vascular facility located at 1625 W. 3rd St., Tempe, AZ and C.R. Bard Inc. facility located at 289 Bay Rd, Queensbury, NY. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body.

We received responses dated December 17, 2014, January 15, 2015, February 18, 2015, March 16, 2015, April 17, 2015, and May 6, 2015, from Mr. Jason J. Gaede, Vice President Plant Operations, C.R. Bard Inc., Queensbury, NY. We also received responses dated January 26, 2015, February 26, 2015, March 26, 2015, April 24, 2015, and May 22, 2015, from Steve S. Williamson, President, Bard Peripheral Vascular, a Division of C.R. Bard, Tempe, AZ. These were responses to the observations noted on Form FDA 483s, Lists of Inspectional Observations that were issued to you at the close of our inspections. We address your responses below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

[redacted]



[redacted]

Quality System Regulation Violations at the Tempe, AZ facility and Queensbury, NY facility

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198(a). Your current procedures governing complaint investigation activities at your facilities, CQA-STD-24 Standard for Product Complaint Handling Rev. 11 and CQA-STD-55, Standard for Complaint Investigation Process Rev. 01, MP9113, Complaint Investigation Activity Rev. 40, SOPQ0153100, BPV Complaint Handling System, Rev. 18, and SOPQ0700200, Complaint Investigation Procedures, Rev. 15 do not ensure product complaints are adequately evaluated. For example:

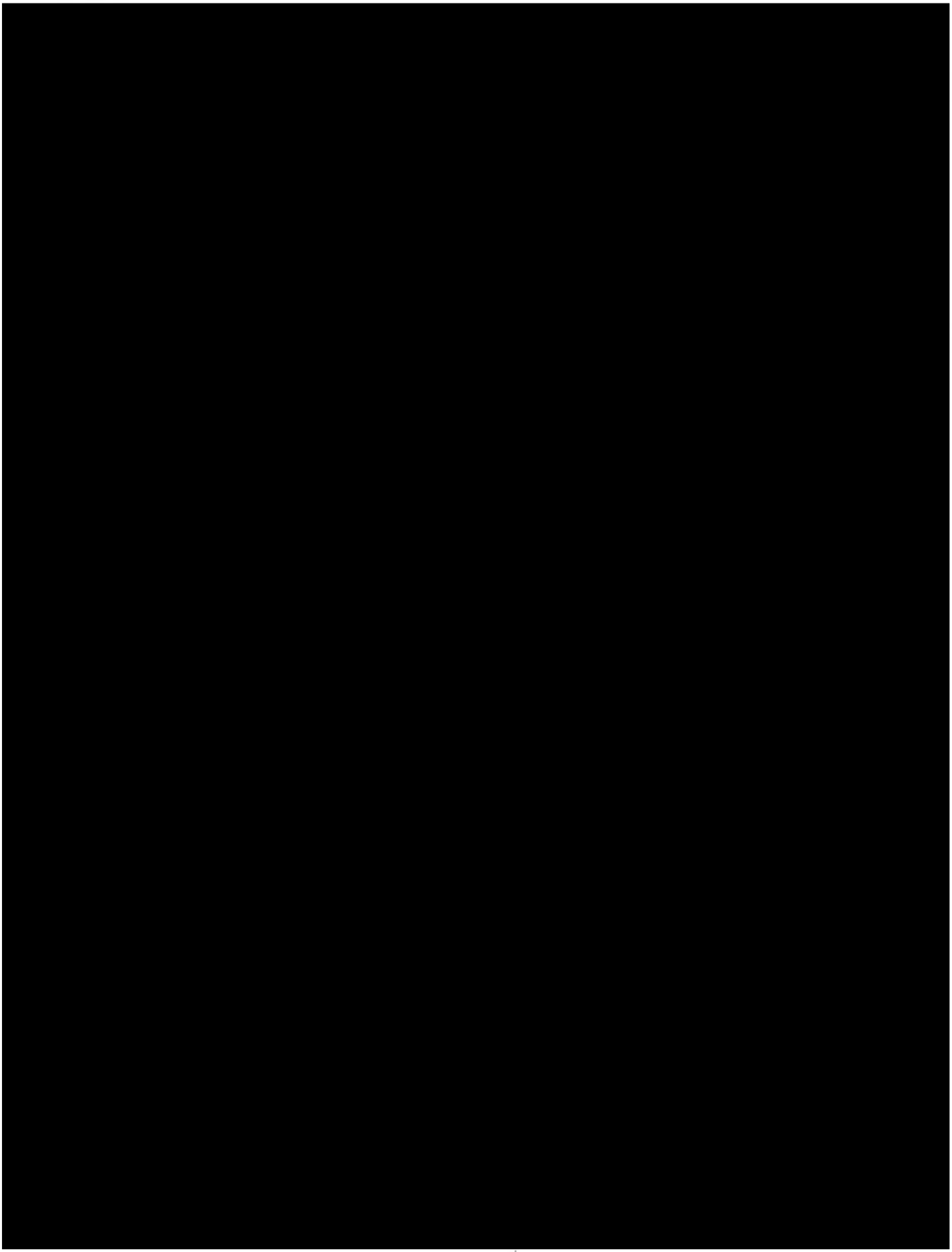
   a. Your current procedures governing complaint investigation activities, CQA-STD-24 Standard for Product Complaint Handling Rev. 11, CQA-STD-55, Standard for Complaint Investigation Process Rev. 01, MP9113, Complaint Investigation Activity Rev. 40, SOPQ0153100, BPV Complaint Handling System, Rev. 18, and SOPQ0700200, Complaint Investigation Procedures, Rev. 15 do not include adequate instructions for ensuring that complaints involving a device or device component provided by a supplier are adequately evaluated for root cause of the alleged device failure and that appropriate corrective action is implemented with your suppliers.

   b. Complaint 562535 for a G2 Filter, embolization of a detached filter arm with associated areas of hemorrhage and necrosis in the right lung was filed as a malfunction Medical Device Report [MDR] and should have been filed as a death. The following complaints were filed as malfunctions and should have been filed as serious injuries: Complaint 628924, Eclipse Filter, detached filter limb resulting in pericardial effusion and cardiac catheterization; 574429, G2 Express

Filter, broken filter and surgical intervention; 602904, Denali Jugular System, detached filter arm embedded in IVC wall with filter retrieval; 443237, G2 Filter, detached filter limb in renal vein with IVC wall perforation and blood thinner treatment; 446809, G2 Express Filter, IVC perforation and aneurysm; 454485, G2 Filter, abdominal pain with filter legs protruding through IVC wall and percutaneous removal; 562566, G2 Filter, abdominal pain with filter legs perforating IVC wall, partial retrieval and residual filter leg fragment embedded in IVC wall.

c. Complaints 507112, 507109, 507115, 507252, 507280, 507302, 507311 and 507325 report at least 10 patients who were exposed to scheduled retrieval surgical procedures to remove an IVC filter that were not successful. However, these complaint files do not document sufficient information to allow for adequate complaint investigation and disposition, including, but not limited to, MDR determination. For example, the complaints do not include information regarding prolonged or repeated surgery that may have occurred as a result of failed attempts to remove the filters, information regarding why the filters were scheduled to be removed and potential complications related to leaving them in the patient due to failed removal, and/or if any additional drugs or anesthetics had to be supplied to the patients.

[redacted]



[redacted]

[redacted]

[redacted]

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality

System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen (15) business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your written response should be sent to the Food and Drug Administration; Attention:

Dr. Raymond W. Brullo
Compliance Officer, Los Angeles District
U. S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

A copy of your written response should also be sent to:

LCDR Catherine M. Beer
Compliance Officer
U. S. Food and Drug Administration
One Winners Circle, Suite 110
Albany, NY 12205

If you have any questions about the content of this letter please contact: Dr. Raymond W. Brullo at (949) 608-2918.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA 483, Inspectional Observations (FDA 483), issued at the close out of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

for
Alonza E. Cruse, Director
Los Angeles District

Cc:

Kevin J. Bovee
Director of Quality Assurance
C.R. Bard, Inc.
289 Bay Road
Queensbury, NY 12804

Jason J. Gaede
Vice President, Plant Operations
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Mark M. Walaska
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bcc:

NYK-DO CB: (Beer/Alexander)
NYK-DO IB: (Frankovic/Terzian/Warner/Izyk)
CFSAN via CMS
HFI-35 (purged) via CMS
Legal file
CMS Case # 453127
EI file C.R. Bard, Queensbury NY (1313046)

LOS-DO DCB file
LOS-DO IB [M. Maxwell, S. Perkins, M. Saale – e-copies]
CMS Case # 453127 [issued version for CO redaction]
Legal File
Factory File
Chron [Brullo]